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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,408	11/30/2006	Leander Grode	2923-737	4545
6449	7590	12/15/2008	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C.			SWARTZ, RODNEY P	
1425 K STREET, N.W.				
SUITE 800			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20005			1645	
			NOTIFICATION DATE	DELIVERY MODE
			12/15/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/554,408	GRODE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 September 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-32 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-17,21-30,32 is/are allowed.
- 6) Claim(s) 18-20,31 and 39-46 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 8 September 2008, is acknowledged. Claims 5, 18, 24 and 31 have been amended. Claims 33-38 have been canceled. New claims 39-46 have been added.
2. Claims 1-32 and 39-46 are pending and under consideration.

### **Rejections Withdrawn/Moot**

3. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for withdrawn in light of the amendment of the claim.
4. The rejection of claims 18-20 under 35 U.S.C. 112, second paragraph, as being indefinite for withdrawn in light of the claim amendments.
5. The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for withdrawn in light of the amendment of the claim.
6. The rejection of claim 31 under 35 U.S.C. 112, second paragraph, as being indefinite for withdrawn in light of the amendment of the claim.
7. The rejection of claims 33-38 under 35 U.S.C. 112, second paragraph, is moot in light of the cancellation of the claims.
8. The rejection of claims 33-38 under 35 U.S.C. 101 is moot in light of the cancellation of the claims.

### **Claim Rejections - 35 USC § 112**

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 18 is now drawn to a cell which further comprises  $\geq 1$  second recombinant nucleic acid encoding a peptide or polypeptide capable of eliciting an immune response in a mammal.

It is unclear what is the function of this second peptide or polypeptide immune response?

Claims 19 and 20 are dependent from claim 18, but do not clarify the identity of said immune response.

11. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 31 is now drawn to a method of producing a cell which further comprises  $\geq 1$  second recombinant nucleic acid encoding a peptide or polypeptide capable of eliciting an immune response in a mammal.

It is unclear what is the function of this second peptide or polypeptide immune response?

12. Newly added claims 39-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 39 is drawn to treating any mammal having any disease state by administering a urease-deficient bacterial cell comprising a recombinant nucleic acid. Claim 40 is the method of claim 39 wherein any mammal has tuberculosis. Claim 41, is the method of claim 39, wherein said any mammal is immunodeficient. Claim 42 is the method of claim 41, wherein any mammal has HIV infection. Claim 43 is the method of claim 39 wherein any mammal has a tumor and the bacterial cell treats the tumor. Claim 44 is the method of claim 39, wherein any mammal has superficial bladder cancer. Claim 45 is the method of claim 39 wherein any animal has any disease state. Claim 46 is the method of claim 39 wherein any human has any disease state.

The specification teaches the manufacture of said bacterial cell, but only treatment of mice or guinea pigs infected with *M. tuberculosis* or *M. bovis* BCG.

Thus, the claims contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed method for treating any mammal having any disease state by administering a urease-deficient bacterial cell comprising a recombinant nucleic acid.

### **Conclusion**

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13. Claims 18-20 and 31 are finally rejected.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

November 24, 2008